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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,026

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Basant Kumar Puri

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27538 7590 06/24/2009

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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

06/24/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,026	<b>Applicant(s)</b> PURI, BASANT KUMAR	
	<b>Examiner</b> LEZAH W. ROBERTS	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47, 49, 50, 52-67 and 69 is/are pending in the application.
- 4a) Of the above claim(s) 53, 66, 67 and 69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47, 49, 50, 52 and 54-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Applicants' arguments, filed April 7, 2009 in the Request for Continued Examination, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claims***

#### **Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejection)**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47-52, 54-63 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite the limitation "less than about." The term "less than" delineates only numerical values more than the recited value where the term "about" may be less than or more than the recited value. Because of the conflict of terms, it is unclear which term is limiting. See also MPEP 2173.05(b) (citing Amgen v. Chugai, 18 USPQ2d 1016 (Fed. Cir. 1991)).

**Claim Rejections - 35 USC § 102 – Anticipation – (Previous Rejection)**

1) Claims 47-50, 52, 54-63, 65 and 68 stand rejected under 35 U.S.C. 102(b) as being anticipated by Horrobin et al. (US 5,145,686). Claims 48 and 68 have been cancelled.

**Applicant's Arguments**

Applicant argues that it cannot be concluded from the disclosure of Horrobin et al. that docosahexanoic acid (DHA) is not present in the disclosed compositions at amounts of less than 0.1%. DHA is a metabolite of eicosapentaenoic acid (EPA) and Horrobin would know that DHA would naturally be present in EPA formulations. Applicant further asserts that Horrobin, in contemporaneous publications, confirms that DHA is a metabolite of EPA. Applicant further submits a document from Chemport Inc. that confirms the natural presence of DHA associated with EPA and the need to purify EPA to exclude the presence of even 1% DHA. The compositions disclosed by Horrobin would naturally comprise DHA because there is no mention of purifying the EPA. This argument is not persuasive.

**Examiner's Response**

The Examiner submits that although the European documents Applicant has cited disclose DHA and EPA, they do not disclose that all formulations of EPA comprise DHA as implied by Applicant. Further the document submitted by Applicant states that

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normal EPA will always have DHA associated with it yet on page 3 it discloses a product rich in EPA having 00% DHA. Therefore forms of EPA without DHA appear to be commercially available. Further the claims recite EPA being incorporated into the recited compositions at concentrations up to a specific amount. The compositions of the reference may comprise 0.01 to 20 percent by weight EPA and Examples disclose EPA comprises 1.0 to 5.0 percent of the exemplified compositions. It appears from the disclosed document that when DHA is present that DHA comprises 1% or more “normally”. Therefore, it is concluded when EPA comprises 0.01 to 1.0 percent of a composition encompassed by the reference, DHA comprises less than 0.1% of the composition as recited in the instant claims because 1% of 0.01% and of 1.0% of EPA is less than 0.1% of the composition. Thus the rejection is maintained.

#### **Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)**

Claims 47, 49, 50, 52 and 54-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin (US 4,977,187) in view of Peet et al. (US 2002/0077361).

Horrobin discloses compositions for treating schizophrenia comprising essential fatty acids (EFAs). The compositions comprise GLA in the form of evening primrose oil (col. 2, lines 11-14). The oil may be extracted from *Oenothera biennis* L. and *Oenothera lamarckiana* (col. 5, lines 23-26), encompassing claim 54. The EFAs include eicosapentaenoic acid (EPA) in a mixture with DHA or purified EPA (see Examples). The EFAs comprise 0.01% to 30% of the compositions. In regards to claim 56, the

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reference does not disclose the primrose oil as being refined and therefor it can be concluded that the oil is a virgin oil, encompassing claim 56. In regards to claims 50, eicosapentaenoic acid is isolated from fish oil (col. 5, lines 13-19). The compositions are formulated into tablets, capsules, ingestible liquid or powder formulations (col. 6, lines 27-28), encompassing claims 61 and 65.

The reference differs from the instant claims insofar as it does not disclose an example comprising primrose oil and EPA without DHA or the purity of EPA after purification.

Peet et al. disclose compositions comprising EPA for treating psychiatric or central nervous disorders including schizophrenia (paragraph 0001). EPA comprises at least 95% of the compositions. It is disclosed that EPA in a purified form is more effective than that dose mixed with other fatty acids that compete with EPA for binding to the relevant sites of action (paragraph 0029). It is further disclosed that DHA reduces the therapeutic effect of EPA and that highly purified EPA is therapeutically more effective (paragraph 0033).

The reference differs from the instant claims insofar as it does not disclose the compositions comprise a triterpene.

It would have been obvious to one of ordinary skill in the art to have purified the EPA of Horrobin to not include DHA or very limited amounts of DHA motivated by the desire to make a composition comprising EPA that is more therapeutically effective than a composition comprising the same amount of EPA with DHA, as disclosed by Peet et al.

Claims 47, 49, 50, 52 and 54-65 are rejected.

Claims 53, 66, 67 and 69 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612